



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,564	10/11/2005	Hiroshi Ueda	026350-095	1114

21839 7590 01/16/2008  
BUCHANAN, INGERSOLL & ROONEY PC  
POST OFFICE BOX 1404  
ALEXANDRIA, VA 22313-1404

EXAMINER
----------

GANGLE, BRIAN J

ART UNIT	PAPER NUMBER
----------	--------------

1645

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

01/16/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com  
debra.hawkins@bipc.com

<b>Office Action Summary</b>	Application No. 10/524,564	Applicant(s) UEDA ET AL.	
	Examiner Brian J. Gangle	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-7, drawn to vectors containing at least following five DNA sequences: (1) a DNA sequence encoding one protein or its fragment; (2) a DNA sequence encoding a protein for displaying said one protein or its fragment on a phage; (3) a DNA sequence encoding another protein or its fragment; (4) a stop codon that enables display switch by a host strain; and (5) a DNA sequence encoding a protein for displaying said another protein or its fragment on the phage, the vector having a structure comprising these 5 DNA sequences in the order of (1), (2), (3), (4) and (5) or (3), (4), (5), (1) and (2) in the 5'-3' direction of the vector, by the presence of the stop codon that enables display switch by said host strain, when the vector is introduced into a suppressor-mutant host strain, the vector provides a two-protein displaying phage on which both of said one protein or its fragment and said another protein or its fragment are displayed, and when the vector is introduced into a non-suppressing host strain, the vector provides a one-protein displaying phage on which only said one protein or its fragment is displayed and said another protein or its fragment is secreted into the culture medium.

Group II, claim(s) 8-18, drawn to methods for determining interaction between one protein or its fragment and another protein or its fragment, comprising 1) transforming a non-suppressing host strain by using the vector according claim 1, thereby obtaining one-protein displaying phage on which only said one protein or its fragment is displayed, and a culture medium containing said another protein or its fragment being secreted from said non-suppressing host strain; (2) immobilizing said another protein or its fragment in the supernatant on an appropriate support; (3) reacting said another protein or its fragment immobilized on the support with said one protein or its fragment displayed on the one-protein displaying phage, thereby said one protein or its fragment is bound to said another protein or its fragment; and (4) determining the amount of immobilized phages by an immunoassay using a labeled anti-phage antibody, thereby evaluating the binding ability between said one protein or its fragment and said another protein or its fragment.

Group III, claim(s) 19, drawn to a method for obtaining a VL fragment of the variable region of an antibody, comprising (1) transforming a non-suppressing host strain by using the vector as described in claim 2, or transfecting a non-suppressing host strain with a VH/VL displaying phage containing said vector; (2) allowing the transformed non-suppressing host strain to secrete the VL fragment into the culture medium; and (3) purifying the VL fragment from the culture medium.

Group IV, claim(s) 20, drawn to a method for obtaining a VH fragment of the variable region of an antibody, the method comprising the steps of: (1) transforming a non-suppressing host strain by using a vector as described in claim 3, or transfecting a non-suppressing host strain with a VH/VL displaying phage containing said vector; (2) allowing the transformed non-suppressing host strain to secrete the VH fragment into the culture medium; and (3) purifying the VH fragment from the culture medium.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-IV appears to be a vector containing at least following five DNA sequences: (1) a DNA sequence encoding one protein or its fragment; (2) a DNA sequence encoding a protein for displaying said one protein or its fragment on a phage; (3) a DNA sequence encoding another protein or its fragment; (4) a stop codon that enables display switch by a host strain; and (5) a DNA sequence encoding a protein for displaying said another protein or its fragment on the phage, the vector having a structure comprising these 5 DNA sequences in the order of (1), (2), (3), (4) and (5) or (3), (4), (5), (1) and (2) in the 5'-3' direction of the vector, by the presence of the stop codon that enables display switch by said host strain, when the vector is introduced into a suppressor-mutant host strain, the vector provides a two-protein displaying phage on which both of said one protein or its fragment and said another protein or its fragment are displayed, and when the vector is introduced into a non-suppressing host strain, the vector provides a one-protein displaying phage on which only said one protein or its fragment is displayed and said another protein or its fragment is secreted into the culture medium.

Janda *et al.* (WO 00/71694, 2000, IDS filed 2/14/2005) disclose cloning vectors which encode a first fusion polypeptide, comprising an exogenous polypeptide fused to the amino terminus of a filamentous phage pVII protein, and a second fusion polypeptide, comprising an exogenous polypeptide fused to the amino terminus of a filamentous phage pIX protein (page 3, lines 19-35). Said exogenous polypeptides are disclosed as immunoglobulin heavy chain variable and light chain variable domains (page 12, lines 7-12). Said vector is designed for phage display of the components of a heterodimeric protein complex (page 2, lines 15-22).

Janda *et al.* do not disclose that the vector should contain a display switch. However, as evidenced by Lucic *et al.* (J. Biotechnol., 61:95-108, 1998, IDS filed 2/14/2005), Hayashi *et al.* (Gene, 160:129-130, 1995), or Lowman *et al.* (Biochem., 30:10832-10838, 1991) it was known in the art that an amber mutation could be inserted between an exogenous protein and a filamentous phage protein so that in a suppressor mutant host, the exogenous protein (such as an antibody) would be displayed on the phage and, in a non-suppressing host, the protein would be secreted. In view of the Supreme Court decision in *KSR International Co. v. Teleflex Inc.*, No. 04-1350 (U.S. Apr. 30, 2007), it would have been obvious to combine elements known in the art

by known methods, where in the combination, each element would have performed the same function as it did separately. In this case, it was well within the skill of the ordinary artisan to introduce an amber mutation in the vector of Janda *et al.* so that one of the fusion polypeptides could be secreted or displayed on the phage, depending on whether the phage was grown in a suppressor mutant. Each of these elements would have performed the same function as they would have separately and the results of the combination would have been predictable.

Therefore, the technical feature linking the inventions of Groups I-II does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the art.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected

process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571) 272-1181. The examiner can normally be reached on M-F 7-3:30.

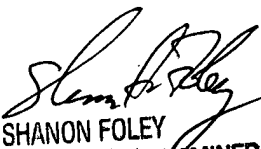
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on (571) 272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number:  
10/524,564  
Art Unit: 1645

Page 6

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brian Gangle  
AU 1645

  
SHANON FOLEY  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600